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Complete If Known Substitute for form 1449A/PTO **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT (use as many sheets as necessary) **Application Number** 10/702,194 Filing Date November 4, 2003 First Named Inventor Solomon et al. Art Unit 3761 **Examiner Name** Keshia GIBSON Sheet of Attorney Docket Number 11973-003

| Examiner | Cite | Document Number | U.S. PATENT DOCU Publication Date | Name of Patentee or | Pages, Columns, Lines, When |
|---------------|--|--|-----------------------------------|---------------------|------------------------------|
| Initials' | No.1 | | MM-DD-YYYY | Applicant of Cited | Relevant Passages or Relevan |
| 1/7 | | Number-Kind Code ² (if known) | | Document | Figures Appear |
| 19 | | 3,860,000 | 01-14-1975 | Wootten et al. | |
| | | 4,315,509 | 02-16-1982 | Smit | |
| | ļ | 4,344,435 | 08-17-1982 | Aubin | |
| | | 4,393,875 | <u>07-19-1983</u> | Nawash et al. | |
| | | 4,553,960 | 11-19-1985 | Lazarus et al. | |
| | <u> </u> | 4,642,092 | 02-10-1987 | Moss | |
| | | 4,723,547 | 02-09-1988 | Kullas et al. | |
| | <u> </u> | 4,899,747 | 02-13-1990 | Garren et al. | |
| | | 5,071,405 | 12-10-1991 | Piontek et al. | |
| | | 5,259,399 | 11-09-1993 | Brown | |
| | | 5,234,454 | 08-10-1993 | Bangs | |
| | | 5,306,300 | 04-26-1994 | Berry | |
| | | 5,520,634 | 05-28-1996 | Fox et al. | |
| | | 5,601,604 | 02-11-1997 | Vincent | |
| | | 5,618,296 | 04-08-1997 | Sorensen et al. | |
| | | 5,741,287 | 04-21-1998 | Alden et al. | |
| | | 5,868,141 | 02-09-1999 | Ellias | |
| | | 6,039,251 | 03-21-2000 | Holowko et al. | |
| | | 6,077,250 | 06-20-2000 | Snow et al. | |
| | | 6,210,347 | 04-03-2001 | Forsell | |
| | | 6,381,495 | 04-30-2002 | Jenkins | |
| | T | 6,447,472 | 09-10-2002 | Moss | |
| | | 6,454,785 | 09-24-2002 | De Hoyos Garza | |
| | | 6,453,907 | 09-24-2002 | Forsell | |
| | | 6,506,179 | 01-14-2003 | Tiefenthal et al. | |
| | \Box | 6,511,490 | 01-28-2003 | Robert | |
| | | 6,579,301 | 06-17-2003 | Bales et al. | |
| | | 6,615,084 | 09-02-2003 | Cigaina | · |
| | | 6,627,206 | 09-30-2003 | Lloyd | |
| | 1. 1 | 6,659,974 | 12-9-2003 | Moss | |
| | | 6,752,790 | 06-22-2004 | Coombs | |
| $\overline{}$ | | 6,755,869 | 06-29-2004 | Geitz | |
| | | -, -, -, -, -, -, -, -, -, -, -, -, -, - | | OCIZ . | |

| | | FOREIGN PAT | TENT DOCUMEN | NTS | | |
|--------------------|--------------------------|---|------------------------------|---|---|----------------|
| Examiner Initials' | Cite No. ¹ | Foreign Patent Document Country Code -Number - Kind Code (if known) | Publication Date MM-DD- YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T [©] |
| KG+ | | WO 01/68007 A1 | 09-20-2001 | | | |
| V | | WO 99/25418 | 05-27-1999 | | | |
| dugs | • | JP200129434 | 02-6-2001 | | | |
| Ka | | JP3-18378 | 01-25-1991 | | | |
| \bigvee | | JP 62-224358 | 10-02-1987 | | | |

| | 1.0% | NON PATENT LITERATURE DOCUMENTS | | | |
|-----------------------|-------|---|--|--|--|
| Examiner Initials* | No. 1 | Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, ma journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country published. | | | |
| KG | | MOSHE SHIKE, MD et al., An Active Esophageal Prosthesis, GastroIntestinal Endoscopy January 1995 Vol. 41 No. 1 | | | |
| | | LAWERENCE L. HERMAN, MD et al., Percutaneous endoscopic gastrostomy for decompression of the stomach and small bowel, Gastronintestinal Endoscopy, 1992 Pgs. 314-318 | | | |
| | | JOSHAU FELSHER,M.D et al., Decompressive percutaneous endoscopic gastrotomy nonmalignant disease, The American Journal Of Surgery 187 (2004) 254-256 | | | |
| | | HENRY BUCHWALD, MD et al., Bariatric Surgery, a Systematic Review and Meta-Analysis, JAMA, OCTOBER 13, 2004-VOL 292, NO. 14 | | | |
| | | MEISSNER K. Hepatogastroenterology. 2004 Mar-Apr;51(56):462-4. Ajuvant surgical decompression gastrostomy: audit of a procedure coming of age. | | | |
| | | MICHAUD L et al., J Pediatr Gastroenterol Nutr. 2001 Jan; 32(1):82-5, Gastrostomy as decompression technique in children with chronic gastrointestinal obstruction. | | | |
| | | HERMAN LL et al., Gastrointest Endosc. 1992 May-Jun; 38 (3): 314-8, Percutaneous endoscopic gastrostomy for decompression of the stomach and small bowel. | | | |
| | | SHIKE M., Oncology (Huntingt). 1995 Jan:9(1):39-44; discussion 44, Percutaneous endoscopic stomas for enteral feeding and drainage. | | | |
| | | SHIKE M et al., JPEN J Parenter Enteral Nutr. 1989 Nov-Dec;13(6):648-50. Skin-level gastrostomies and jejunostomies for long-term enter feeding. | | | |
| · | | NASSIF AC. Obes Surg. 1991 Mar;1(1):99-102., Efficient Decompression and Immediate Enteral Hyperaliment via Gastrostomy as an Adjunct to Gastroplasty | | | |
| | | SHIKE M, Gastrointest Endosc. 1990 May-Jun:36(3):290-2. Combined gastric drainage and jejunal feeding through a percutaneous endoscopic stoma. | | | |
| | | MOSEH SHIKE, MD et al. External biliary duodenal drainage through a percutaneous endoscopic duodensotomy, Gastrointestinal Endoscopy, volume 35, no. 2, 1989 | | | |
| | | MOSHE SHIKE, MD et al., Percutaneous endoscopic gastrostomy and jejunostomy for long-term feeding in patients with cancer of the head and neck, otolaryngology Head and Neck Surgery Vol. 101 (5), 1989. | | | |
| | | T. LORENTZEN et al., Percutaneous Gastrostomy guided By Ultrasound and Fluorscopy ACTA Radiologica 36 (1995) 159-162 | | | |
| | | Francesco Doenz et al., Versatility of the Proximal Cope Loop Catheter, American Journal of Roentgenolog January 1989, 205. | | | |
| | | K.E. GEHMAN et al. Percutaneous Gastrojejunostomy with a Modified Cope Loop Catheter, American Journal of Roentgenology 155.79-80 (1990) | | | |
| | | ROBIN R. GRAY, MD, et al., Modified Catheter For Percutaneous Gastrojejunostomy RADIOLOGY 1989; 173:276-278. | | | |
| | | RICHARD DUSZAK, JR. MD, PERCUTANEOUS GASTROSTOMY AND JEJUNOSTOMY http://www.emedicine.com/radio/topic798.htm (7/8/2005) | | | |
| | | KATHERINE M. FLEGAL, PhD et al. Prevalence and Trends in Obesity Among US Adults, 1999-2000 JAMA, October 9, 2002 Vol 288, No. 14, 1723-1727 | | | |
| | | ANDREW LUCK AND PETER HEWETT Lapraoscopic Gastrostomy: Towards The Idea Technique Aust. N.Z. J. Surg. (1998) 68,281-283. | | | |
| | | F.J. THORNTON et al., Percutaneous Radiologic Gastrostomy With and Without T- Fastener Gastropexy: A Randomized Comparison Study CardioVascular Interventional Radiology (2002) 25:467-471 | | | |
| V | | OZMEN et al. Percutaneous Radiologic Gastrostomy, European Journal of Radiology 43 (2002) 186-195. | | | |

| Examiner Signature | Date Considered | 8/2/06 |
|-----------------------|--------------------|--------|

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| 1/01 | Number-Rind Code | | | |
|--------------------|--------------------------|---------------|------------------|--------------------|
| KG | ^{US-} 3,884,808 | 05-20-1975 | Scott | |
| 7-71 | US- 3,924,625 | 12-09-1978 | Peterson | |
| | US- 4,082,095 | 04-04-1978 | Mendetson et al. | |
| - | US- 4,116,589 | 09-26-1978 | Rishton | |
| | US 4,449,972 | 05-22-1984 | Kruger | |
| - , - | US- 4,642,092 | 02-10-1987 | Moss | |
| -\/- - | US- 5,411,022 | 05-02-1995 | McCue et al. | |
| | US- | | | |
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Applicant

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| Filing Date | Group Art Unit |
| November 4, 2003 | 3761 |
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(Use several sheets if necessary) **U.S. PATENT DOCUMENTS** Examiner **Document Number** Date Name Class Sub **Translation** Initial Class FOREIGN PATENT DOCUMENTS Examiner **Document Number** Class Date Country Sub Translation **Initial** Class OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.) Goldstein DJ., Beneficial health effects of modest weight loss, Int J Obes 1992 16:397-415. **Date Considered** Examiner

Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP§60: Draw line through citation if not in conformance and not considered, include copy of this form with next communication to the patent owner.